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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,481	07/18/2003	Jong Lim	015662-002100US	4558

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,481	LIM ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,40,41 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,40,41 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Paper Received: Response dated 11/02/06.

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

2. The first drug released:

   a. Loop Diuretics

   b. Thiazide diuretics

   c. Potassium-sparing diuretic

   d. Sulfonylurea compounds

3. The second drug released:

   e. ACE inhibitors

   f. Angiotensin II antagonists

   g. Antibiotics of 40

   h. Antidiabetic agents of claim 40 and 41

4. The species are independent or distinct because each class of drug named in the claims has different properties and functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 29 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Applicant's election with traverse of the species election in the reply filed on 9/28/06 is acknowledged. The traversal is on the ground(s) that the claims are more drawn to the release of the active agents and their formulation not the specific functionality of the individual drugs. This is not found persuasive because the disparity in subject matter in the claimed drugs represent a burden on the examiner since each group of drugs is classified separately and would represent a separate and independent search.

The requirement is still deemed proper and is therefore made FINAL.

Applicant has elected species corresponding to claims 1-28,40,41 and 43-46.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-28,40,41 and 43-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,682,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to a method of making a pharmaceutical tablet comprising dispersing a first drug solution onto a substrate making a unitary dosage form, depositing on the unitary dosage a polymeric layer, and depositing over that layer a second drug solution, nest evaporating the solvent. The '759 patent claims are drawn an identical process save for a ratio of first to second drug. There is essentially no difference between the instant claims and the '759 patent. The '759 patent would act as obviating art over the instant claims if issued.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Johnson et al (USPN 6,171,618 hereafter '618). The claims are drawn to a method of making a pharmaceutical dosage form comprising depositing a first drug onto a matrix, depositing successive layers of controlled releasing polymers and a second drug onto the matrix, followed by driving off any solvents used.

13. The '618 patent is drawn to a method of making a combination dosage form comprising two separate drugs having different release rates (abstract). The first drug (the controlled release agent) is released so that at least 75% of the drug is released over a period of 4-36 hours (col. 3, lin. 10-15). The first drug is formed into a core with a solid matrix material such as microcrystalline cellulose and hydroxypropyl cellulose (col. 17, lin. 50-55). The core is then coated with a solution of a polymer matrix not comprising a drug and can fully encompass the core or cover sections having pores (col. 18, lin. 5-10; col. 10, lin. 8-68). The resultant coated core is further coated with a drug formulation (col. 18, lin. 30-40). The tablets are dried leaving a solid two drug controlled release agent with the top drug formulation releases immediately while the inner coated drug releases slower (examples). Solvents include water, ethanol and acetone

(example). The weight ratio of the polymeric film to the unitary body (core) is approximately 0.16:1 (example 2).

14. The reference differs from the instant claims in disclosures of the ratio of unitary dosage from to the polymeric film, however this limitation is well within the limits of one of ordinary skill in the art to manipulate and arrive at through routine experimentation. The reference is further silent to the specific amount of first drug is release within the first hour. Although 75% of the drug is release over a period of 4-36 hours, there are no explicit disclosures for the first hour. However it is the position of the Examiner that this release rate like many properties can be manipulated and derived from routine experimentation. As discussed above the ratio of polymeric film to unitary dosage overlaps the range of the instant claims (0.16:1). It is the position of the Examiner that these specific ratios represent an optimized result determined through routine experimentation and do not impart patentability on the claims.

15. With the things in mind it would have been obvious to one of ordinary skill in the art to follow the suggestions of the art to follow the teachings and suggestions of the art in order to provide a stable combination therapy useful in treating various disorders. One of ordinary skill in the art would have been motivated to follow these teachings with an expected result of a combination therapy useful in treating various disorders.

16. Claims 40,41 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Johnson et al (USPN 6,171,618 hereafter '618) in view of Timmins et al (USPN 6,031,004 hereafter '004) and Sauerberg et al (USPN 6,274,608 hereafter '608).

17. As discussed above the '618 patent discloses a combination therapy wherein the separate drugs have distinct release profiles. The reference differs in the specific drugs recited however the inclusion of specific agents is a pharmaceutical dosage form is well within the level of skill in the art as seen in the '004 and '608 patents.

18. The '004 patent discloses a combination therapy comprising metformin salts and sulfonylurea agents (abstract). The sulfonylurea agents include glyburide, glimepiride, glipyride, glipizide and other well-known diabetic treatment agents (col. 4, lin. 24-28). The metformin salts include hydrochloride (col. 4, lin. 59-68). It would have been obvious to combine the drugs into the formulation of the '618 patent since both formulation comprise similar cellulose based controlled releasing agents.

19. The '608 patent discloses a combination therapy comprising various ACE inhibitors and sulfonylurea compounds. The ACE inhibitors include benazepril, captopril and ramipril (col. 12, lin. 20-30), while the sulfonylurea agents include metformin (col. 12, lin. 10-17). The formulation further comprises cellulosic materials as controlled releasing agents (col. 13, lin. 50-60). It would have been obvious to combine the drugs of patent into the '618 patent since they both comprise similar control releasing agents.

20. With these aspects in mind it would have been obvious to combine the specific drugs of the '608 and '004 patent into the formulation of the '618 patent in order to impart specific therapeutic properties on the formulation. One of ordinary skill in the art would be motivated to combine the teachings with an expected result of a combination therapy capable of treating various disorders.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER